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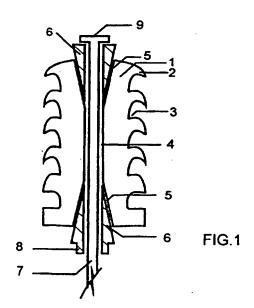
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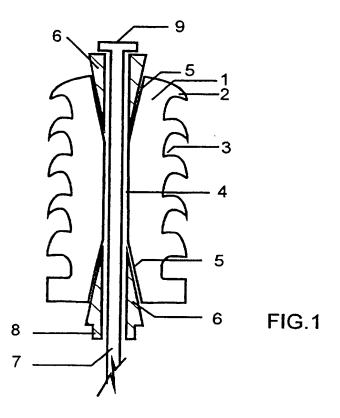
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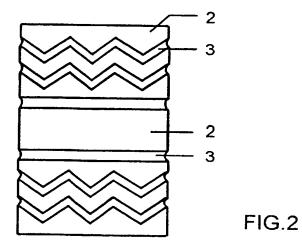
- (54) Abstract Title Cement restrictor
- (57) The cement restrictor, for use in joint or bone prosthesis implantation, comprises a substantially cylindrical annular body 1 dimensioned to be inserted into a cavity formed within a bone. The restictor is of such deformable material that it is adapted to be radially expanded in situ to engage the walls of the cavity. A pair of substantially rigid block members 6, one located at each end of the body, may be drawn, one towards the other. Force applied in an axial direction and at a point above the restrictor causes radial expansion of the body. The block members are locked when drawn towards one another.



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995





CEMENT RESTRICTER

The present invention relates to a cement restricter. More particularly, but not exclusively, it relates to a cement restricter which can be forced to expand to contact the walls of a cavity formed during osteal prosthesis implantation.

During such implantation operations, a hole is drilled into the bone to a predetermined depth. For convenience, the invention will be described by way of its use in relation to a femur, on which treatment is required in the case of hip joint replacements. However, the restricter device may find application for other uses with other bones in other prosthetic operations.

During a prosthesis implantation operation, a hole is drilled into the medulla of the femur to a predetermined depth, the depth being determined by the length of the prosthesis to be inserted. The prosthesis will be held in place by means of bone cement, which comprises beads of polymethylmethacrylate coated in a methylmethacrylate monomer, which cures in situ to form a unitary mass. Problems can occur at the lower end of the cavity where the bone marrow exposed by the excavation comes into contact with the bone cement. It is therefore advisable to place a plug of some sort into the bottom of the cavity to separate the two. However, the exact shape and radial size of the cavity at its lowermost point cannot be predetermined and therefore, even with a number of sizes of cement restricter, it is almost impossible to find one which will fit exactly and sea! within the space.

It is an object of the present invention to provide a cement restricter which can be placed into position and deformed to form a good seal with the walls of the bone at that point of the cavity.

According to a first aspect of the present invention, there is provided a cement restricter for use in joint or bone prosthesis implantation comprising a substantially cylindrical annular body dimensioned to be inserted into a cavity formed within a bone and being of such deformable material that it is adapted to be radially expanded in situ to engage the walls of the cavity, a pair of substantially rigid block members, one located at each end of the body, means to draw said block members one towards the other by force applied in an axial direction and at a point above the restricter thereby to cause radial expansion of the body, and means to lock together said block members when drawn towards one another.

The force may be applied by means of a longitudinally extending draw member, which draw member also forms part of the locking means.

The draw member may be connected to an innermost, with respect to the cavity, block member and complementary parts of the means to lock may be provided on an outermost block member or an outermost end of the body to maintain the body in an axially compressed and radially extended disposition.

The lock may comprise a pawl provided in or integral with the outermost block member and cooperable with any one of a series of ratchets provided on the draw member.

The material of the body is preferably biodegradable once in situ, and may comprise a material such as gelatin or collagen, or a modified analogue thereof.

The external periphery of the body is preferably provided with an uneven surface for engagement with the inner walls of the cavity.

The external peripheral surface may comprise one or a plurality of grooves extending around respective circumferences of the body.

In this case, the grooves may be, in axial cross section, square, triangular or of barbed form.

The grooves may be parallel one to another.

Alternatively or additionally, any one or more of the grooves may be axially variable around the periphery of the body, in such forms as chevrony, wavy, embattled or the like.

The central aperture of the cylindrical annular body may be enlarged at one or both ends into a frustoconical, curved or otherwise widening cavity.

One or both of the pair of block members may be frustoconical, and may be provided at a respective end of the body to cooperate with the widened cavity whereby movement inwardly with respect to the body of one or both block members will cause radial expansion of the periphery of the body.

The or each block member may be of polymethylmethacrylate (PMMA) or bone cement.

According to a second aspect of the present invention, there is provided a method of restricting bone cement penetration within a cavity, comprising the steps of inserting therein to a predetermined depth a cylindrical annular body of deformable material, providing therein a plug cooperable within the annulus of the body to expand it radially and a draw member connected to the plug and adapted to extend out of the cavity, and pulling said draw member while steadying an outermost end of the body to cause axial compression of said body thereby to expand it radially to engage the walls of the cavity.

Embodiments of the invention will now be more particularly described by way of example and with reference to the accompanying drawings, in which:

Figure 1 shows in cross-section a cement restricter embodying the invention; and

Figure 2 shows in elevation another embodiment of cement restricter.

Referring now to the drawings, the restricter shown in figure 1 comprises a cylindrical annular body 1, preferably of biodegradable material such as gelatin or collagen or a

modification thereof, which is deformable under pressure. The outside periphery of the cylinder is formed to have a number of ridges 2 and furrows 3. These may be axially parallel or, as shown in figure 2 they may be axially variable. The form of the axial variability may be chevrony, as shown in figure 2 or may take other forms such as wavy, embattled, unduly or any other appropriate form.

The centre aperture 4 of the cylindrical annular body 1 is tapered outwardly at each end 5 to form a substantially conical zone.

A pair of plugs 6, of substantially non-deformable material, such as bone cement, each have a frustoconical form adapted to fit generally within the conical outlet of the central aperture of the cylinder 1. A draw member 7 extends through the aperture 4 and is anchored at 9 beyond the innermost one of the frustoconical plug members 6. The anchor may pass through the innermost frustoconical member or may be integral therewith, and therefore anchored to it. The draw member 7 passes through the outermost frostoconical member 6 via a locking device 8. In this, a pawl is provided which co-operates with any one of a series of ratchets provided on the draw member 7.

In operation, the cement restricter is inserted into a cavity drilled into the bone, either for implantation or revision of a prosthesis, or indeed for any other purpose, and once in place, it can be maintained in situ by means of a probe while the draw member 7 is pulled to cause the two frustoconical members 6 to move towards one another and be locked in a closed-up position by means of the locking member 8. The inward movement of these two members causes the material of the cylindrical annulus 1 to expand radially outwardly and thereby contact the interior wall of the bone cavity in which it is situated. The material is sufficiently deformable to take account of non-circular cavities, especially since the restricter has a grooved outer periphery, enabling it to deform more easily.

Once the cement restricter device is in position, and locked by interaction of a ratchet of the draw member 7 with the pawl, the excess length of the draw member 7 is cut and removed. The cement and prosthesis can then be inserted into the cavity after which the device, if made of biodegradable material will eventually be degraded by bone marrow.

The material of the cylinder I is sufficiently deformable to accommodate variations in diameter of the bone cavity when it is expanded by longitudinal compression. Hence, provided that the approximate diameter of the cavity is known, an appropriate cement restricter may be selected, inserted and expanded to seal the cavity.

CLAIMS

- 1. A cement restricter for use in joint or bone prosthesis implantation comprising a substantially cylindrical annular body dimensioned to be inserted into a cavity formed within a bone and being of such deformable material that it is adapted to be radially expanded in situ to engage the walls of the cavity, a pair of substantially rigid block members, one located at each end of the body, means to draw said block members one towards the other by force applied in an axial direction and at a point above the restricter thereby to cause radial expansion of the body, and means to lock together said block members when drawn towards one another.
- 2. A cement restricter as claimed in claim 1, wherein said force is applied by means of a longitudinally extending draw member, which draw member also forms part of the locking means.
- 3. A cement restricter as claimed in either claim 1 or claim 2, wherein the draw member is connected to an innermost, with respect to the cavity, block member and complementary parts of the means to lock are provided on an outermost block member or an outermost end of the body to maintain the body in an axially compressed and radially extended disposition.
- 4. A cement restricter as claimed in any one of the preceding claims, wherein the locking means comprises a pawl provided in or integral with the outermost block member and cooperable with any one of a series of ratchets provided on the draw member.
- 5. A cement restricter as claimed in any one of the preceding claims, wherein the material of the body is biodegradable once in situ, and comprises a material such as gelatin or collagen, or a modified analogue thereof.
- 6. A cement restricter as claimed in any one of the preceding claims, wherein the external periphery of the body is provided with an uneven surface for engagement with the inner walls of the cavity.

- 7. A cement restricter as claimed in any one of the preceding claims, wherein the external peripheral surface comprises one or a plurality of grooves extending around respective circumferences of the body.
- 8. A cement restricter as claimed in any one of the preceding claims, wherein the grooves are, in axial cross section, square, triangular or of barbed form.
- 9. A cement restricter as claimed in any one of the preceding claims, wherein the grooves are parallel one to another.





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GB 9708993.2

Claims searched: 1-9

Examiner:

Peter Davey

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20 August 1998

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5R (RAM, RAP)

Int Cl (Ed.6): A61F 2/30 2/46

Other: Online: WPI, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2253564 A	(THACKRAY), see eg. claim 1	1 at least
X	US 4447915	(SULZER), see eg. claim 1	1 at least
<u> </u>			

X Document indicating lack of novelty or inventive step
 Y Document indicating lack of inventive step if combined with one or more other documents of same category.

[&]amp; Member of the same patent family

A Document indicating technological background and/or state of the art.

P. Document published on or after the declared priority days but before

P Document published on or after the declared priority date but before the filing date of this invention.

E Patent document published on or after, but with priority date earlier than, the filing date of this application.